

Application No. 10/081,478
Amdt. Dated October 12, 2004
Reply to Office Action of April 27, 2004

Amendment to the Specification:

1. On page 6, please replace the first paragraph with the following amended paragraph:

It is a further object of the invention to provide a GTR membrane of the above type in which respective upper and lower surfaces thereof are particularly physically and chemically optimized to establish stable interfaces with soft and hard tissue upon respective sides thereof such that, during healing, soft tissue will not interfere with the normal or desired mode of healing of hard or bone tissue at an *in vivo* wound site.

2. On page 10, please replace the second paragraph with the following amended paragraph:

A wide variety of biodegradable, biologically acceptable materials are known in the art which may serve as a substrate for the material of the instant GTR membrane. Many of these materials are polymeric and include materials such as polylactic acid homopolymers, polyglycolic acid co-polymers, combinations thereof, polylactones, polypeptides, polyvinyl alcohols and natural polymers such as collagen, and polysaccharides, Hench's bioglass, fibrinogen and polyimino-carbonate. In the case of homopolymers, corresponding copolymers with other such materials may also be employed.

3. On page 10, please replace the third paragraph with the following amended paragraph:

In one embodiment of the invention, namely, that shown in Fig. 1, the diameter of the substantially circular GTR membrane is that of about 12 millimeters (slightly less than 0.5 inches) and, as above noted, will have a width

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thickness in a range of 200 to 500 microns (0.2 to 0.5 millimeters). The weight of the biodegradable material is in a range of 1 to 5 grams/cm².

4. On page 11, please replace the first paragraph with the following amended paragraph:

Said GTR membrane 10 includes an upper or soft tissue side 12 and a lower or hard tissue side 14 (see Fig. 1). Research over the last ten years (see Reference to Related Applications) has indicated that certain micro-textured surfaces, and certain specific geometries thereof are more effective in the establishment of a stable soft tissue interface than are others. More particularly, as is shown in the enlarged ~~magnified~~-schematic views of Figs. 2, 3, 13 and 17, it is believed that a so-called micro-post surface having six micron grooves, post widths and post heights will establish a stable interface between the GTR membrane 10 and soft tissue that surface 12 is contacted with. It is therein to be appreciated that the specific micro-texture or geometry of surface 12 will be considerably dictated by the type of soft tissue of interest. However, in general, the function of micro-posts 16 is that of effecting a cytophobic separation between posts 16 that corresponds to the morphology of individual cells or small groups thereof, thereby permitting the efficient integration of the micro posts into a normal healing or tissue regeneration pattern of the soft tissue itself. In ~~generally-general~~, cells or soft tissue such as cells of the gum and epithelium ~~has~~ have been found to fall in a range of 1 to 8 microns. As such, this range would generally dictate the dimensionality of said grooves, post widths and post heights shown in Figs. 2 and 3. Also, by defining such cytophobic regions for specific tissue, undesirable other tissue is excluded from interface with soft tissue side 12 of the GTR membrane 10.

5. On page 12, please replace the second paragraph with the following amended paragraph:

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In general, most wounds or bone defects 19 to be repaired will have a definable center 20. See Figs. 6 to 8. It is accordingly a strategy in the design of the instant GTR membrane to provide a corresponding center point 22 (see Figs. 4 and 6) of side 48 14 to which the geometry of channels 24 is directed to encourage a maximum ingrowth of bone tissue towards center 20 of the wound or bone defect. In a preferred embodiment, it has been determined that channels 24 may have a primary dimension of 12 microns as the width and height of the microstructure 18 with separations 26 of similar dimensions therebetween. Such a 12-micron dimension is reflective of our research of many years which indicate that ~~eseoblast~~ osteoblast cells are generally of greater size and than are epithelial and muscular cells. Accordingly, a greater dimensionality of the ~~microtexturing~~ microtexture of lower side 14 will be more appropriate relative to that of said upper side 12, this typically in a range of 10 to 25 microns.

6. On page 13, please replace the second paragraph with the following amended paragraph:

It is also to be appreciated that membrane 28 10 may also serve as a spacer and surgical packing means in many procedures.

7. On page 14, please replace the first paragraph with the following amended paragraph:

In Figs. 9 to 14 are shown the range of potential surface geometries for either upper or lower surface ~~46 or 48~~ 12 or 14, and in Figs. 15 to 22 ~~[[s]]~~ are shown a variety of vertical cross-sectional geometries, ~~the~~ The views of Figs. 13 and 17 correspond to the views of Figs. 3 and 5 above, ~~each~~ Each of these subject to the limitation that soft tissue will generally require a smaller scale of ~~micro-texturization~~ micro-texturization than will that of bone tissue. In one

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embodiment, grooves and ridges upon the upper surface 12 have a width and a height of about 2 to about 10 microns, and those upon the lower surface 14 have a width and a height of about 8 to about 25 microns.